

# EXHIBIT S



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services  
Administration

Rockville, MD 20857  
Healthcare Systems Bureau

JUN - 8 2018

Motty Shulman, JD  
Boies Schiller Flexner, LLP  
333 Main Street  
Armonk, NY 10504

Dear Mr. Shulman:

Thank you for your letter concerning the Organ Procurement and Transplantation Network (OPTN) Liver Allocation Policy both as currently implemented and as modified by changes approved by the OPTN Board of Directors in 2017.<sup>1</sup> The Health Resources and Services Administration (HRSA) oversees the OPTN, which develops organ allocation policies through a deliberative process with input from experts in the field, transplant candidates and recipients, donor and recipient families, living donors, and the public.

As we believe you are aware, the allocation of livers procured in New York is currently governed by the Region 9 variance to the OPTN Liver Allocation Policy. In addition, the revised Liver Allocation Policy approved in 2017 incorporates a revised Region 9 variance, set forth in revised OPTN Policy 9.11.C. This revised Region 9 variance is described in a briefing paper presented to the OPTN Board of Directors in December 2017. Please see OPTN Briefing Paper, Enhancing Liver Distribution, pages 25-28, 55 (available at [https://optn.transplant.hrsa.gov/media/2329/liver\\_boardreport\\_201712.pdf](https://optn.transplant.hrsa.gov/media/2329/liver_boardreport_201712.pdf)).

HRSA considers your letter a critical comment under 42 CFR 121.4(d). Consistent with that provision and to inform HRSA's consideration of the critical comment, HRSA has requested that the OPTN provide its views on the issues raised in your letter, including whether certain aspects of the revised OPTN Liver Allocation Policy are consistent with the requirements of the National Organ Transplant Act of 1984, as amended, and the OPTN final rule.

Sincerely,

  
George Sigounas, MS, Ph.D.  
Administrator

cc: Yolanda Becker, MD, OPTN/UNOS President

<sup>1</sup> Such changes have not yet been implemented, pending computer programming.